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⑥ References cited:
EP-A-0 105 677 US-A-2 074 634
WO-A-80/02108 US-A-4 140 130
WO-A-81/03616 US-A-4 375 220
DE-A-3 011 322 US-A-4 378 806

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Philadelphia, US, J.B. MARMAOR, G.M. HAHN
"Combined Radioation and Hyperthermia in
Superficial Human Tumors", pages 1986-1991

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EUROPEAN JOURNAL OF CANCER, vol. 12, no.
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Description

The present invention relates to hyperthermia generally and more particularly to a technique and apparatus for hyperthermic treatment of tumors in the vicinity of the anal body cavity.

The use of hyperthermia in treatment of malignant tumors is well known and is documented in a large number of scientific reports. Recent summary reports which reflect the activity in this field appear in:

1. Manning, M. R.; Cetas, T. C.; Miller R. C.; Oleson, J. R.; Connort, W. G.; Gerner, E. W., Clinical Hyperthermia; Results of a Phase I Trial Employing Hyperthermia Alone or in Combination with External Beam or Interstitial Radiotherapy, *Cancer* Vol 49, pp 205—216, 1982.

2. Overgaard, J. Fractionated Radiation and Hyperthermia, *Cancer*, Vol 48, pp. 1116—1123, 1981.

A brief summary of the research carried out by the present applicants appears in a preprint entitled:

3. Yerushalmi, A.; Servadio, C.; Fishelovitz, Y.; Leib, Z.; Rankowsky, A.; Stain J. A.; Local Hyperthermia for Treatment of the Prostate: A Preliminary Report, *Prostate*, 3; 623—630, 1982.

It has been appreciated by applicants that a major limitation to the successful application of hyperthermia has been the undesired heating of healthy tissue in the vicinity of the tumor. Efforts have been made to solve this problem for superficial tumors. See Marmor J. B.; Hahn, G. M.; Combined Radiation and Hyperthermia in Superficial Tumors. *Cancer* Vol. 46, pp 1986—1991, 1980.

Apparatus for hyperthermic treatment including a probe member which is adapted to be inserted into a body cavity, wherein the probe includes an RF microwave antenna and means for circulating a cooling fluid through the probe, is known as are devices for monitoring the temperature adjacent the probe and at the heating target location for controlling the operation of the antenna and cooling mechanisms. References showing such apparatus appear in US—A—2 074 634, 4 237 898, 4 140 130 and 4 290 435.

US—A—4 375 220 discloses an apparatus suitable for hyperthermic treatment of tumors in the vicinity of the anal body cavity wherein the cavity mucosa and the cavity walls are cooled while simultaneously heating said tumors. Said apparatus comprises probe means arranged to be insertable into the body cavity and including: a housing having forward and rearward surfaces; radiation-producing antenna means disposed in said housing; and cooling conduit means disposed peripherally of said housing and arranged to receive cooling fluid for cooling body tissue disposed in propinquity thereto, said cooling conduit means comprising a flexible conduit.

The present invention seeks to provide an apparatus for hyperthermic treatment of tumors which seek to overcome the well known problems of undesired heating of tissue.

This is achieved in apparatus of the just

described type by said flexible conduit being coiled about the outside forward peripheral surface of said housing, whereby it may be compressed upon insertion into the anal cavity and expanded forwardly of the sphincter muscle when coolant passes therethrough for secure engagement in said cavity, thus retained by the sphincter muscle.

Embodiments of the invention are claimed in the dependent claims.

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a generalized block diagram illustration of hyperthermic treatment apparatus constructed and operative in accordance with a preferred embodiment of the present invention when the probe of figures 2 and 3 is considered.

Fig. 2 is a pictorial illustration of an alternative configuration of probe constructed and operative in accordance with an embodiment of the invention;

Fig. 3A is a side view illustration of a preferred embodiment of a probe assembly; and

Fig. 3B is a cross sectional view of the forward section of Fig. 3A.

Reference is now made to Fig. 1 which illustrates apparatus for hyperthermic treatment of tumors constructed and operative in accordance with a preferred embodiment of the present invention. Throughout the specification and claims, the term "tumor" will be used in a general sense to mean both benign and malignant tumors. The apparatus is based on a probe 10, illustrated in exemplary form in Figs. 2 and 3, and which includes radiation emitting antenna means and cooling fluid conduit means. Temperature sensing means 12 may also be incorporated in one or more of the fluid conduit means. Additionally, temperature sensing means 12, such as a thermocouple or another substantially non-perturbing temperature sensor may be disposed on the outer surface of the probe and enclosed together with the probe in a suitable protective sheath. An additional temperature sensor 12 is provided interiorly or adjacent to the tumor sought to be treated.

Probe 10 is designed to be readily easily insertable into the rectal cavity, preferably without requiring sedation of the patient undergoing treatment. Temperature sensors 12 are connected via a multichannel multiprobe unit 13 that provides time shared scanning of sensors 12 to a thermometer 15, which provides an output indication of the measured temperatures at the various sensors.

A radiation generating unit is provided and includes a step-motor controlled power control unit 14 such as a standard unit manufactured by Hewlett Packard of the U.S.A., a radiation generator 16, typically a microwave generator such as a CMD 12 manufactured by Raytheon of the U.S.A., a tuning and matching network 18 according to the frequency and impedance used, such as a conventional unit manufactured by

Omnispectra of the U.S.A., a Forward/Reflected Power Meter 20, such as a unit manufactured by Hewlett Packard and one or more antennas such as an antenna manufactured by RCA Inc. of the U.S.A. incorporated within probe 10.

A coolant circulation unit 22 is maintained in fluid communication with fluid conduit means within probe 10 by means of a pair of flexible conduits 24.

A minicomputer 26, such as a HP 9825B, controls the overall operation of the apparatus and provides control signals to the power control unit 14, and the circulation unit 22, while receiving status inputs from thermometer 15 and free probe 10. Failsafe logic circuitry 28 provides automatic termination of radiation in the event of a malfunction in any of the major operating systems, including the power control unit 14, the generator 16, the temperature sensing means 12 or the probe 10. Failsafe circuitry 28 is also operative to provide immediate termination of radiation in the event of sensed overheating at temperature sensing means 12.

Also communicating with minicomputer 26 are various recording devices and memory devices for maintenance of records. These may include conventional data acquisition and storage means 30, a plotter 32 and a printer 34.

It is noted in general that producing intratumor temperatures above 41 degrees centigrade is selectively lethal to radiation resistant cells, (See Giovanella, B. C.; Stehlin, J. S.; Morgan, A. C.; Selective Lethal effect of Supranormal Temperatures on Human Neoplastic Cells, *Cancer Research* Vol 36, pp 3944-3950, 1976.), and hypoxic cells (See Gerner E. W.; Holmes, P. W.; McCullough, J. A., Influence of Growth State on Several Thermal Responses of EMT6/A7 Tumor Cells in vitro, *Cancer Research* Vol 39, 981-986, 1979.) Synergism of hyperthermia with radiation and drug therapy is described in the following references: Yerushalmi, A.; Treatment of Solid Tumor by Local Hyperthermia and Ionizing Radiation; Dependence on Temperature and Dose, *European J. Cancer* Vol 12, pp 807-812, 1976 and Yerushalmi, A., Combined Treatment of a Solid Tumor by Local Hyperthermia and Actinomycin-D. *Br. J. Cancer* Vol 37, pp 827-832, 1978.

The operation of the apparatus of Fig. 1 will now be described briefly. Initially the predetermined temperature to be achieved at the tumor during treatment and maximum permissible tissue temperatures are selected by the operator.

The principle of operation of the apparatus of Fig. 1 is that the output energy of the microwave generator is increased in a stepwise fashion on the basis of frequent temperature measurements at, or in the vicinity of, the tumor. If between measurement samples, the temperature at the tumor is seen to rise, the output energy is not increased. In such a case, the output energy is maintained at the same level while the temperature is repeatedly sampled until the temperature is found not to increase between samples.

Fail safe operation is provided by sensing the

temperature in the cooling fluid and also at the tissue location adjacent the probe along the radiation pathway from the antenna to the tumor. The temperature thus sensed is representative of the maximum possible temperature produced in the normal tissue adjacent the probe.

Fig. 2 is a pictorial illustration of an embodiment of a probe. Here the cooling fluid conduit 98 is provided along the outer surface of the probe housing 100, typically in the form of a helix.

Reference is now made to Figs. 3A and 3B which illustrate a preferred embodiment of the present invention incorporating an externally disposed coolant circulation conduit as illustrated in Fig. 2. Fig. 3A is a side view illustration of a probe assembly 101 including a broadened forward section 102, a narrowed intermediate section 104, a handle portion 106 and a coaxial antenna connection 107. Fig. 3B is a cross sectional illustration of the forward section 102.

The probe of Figs. 3A and 3B comprises a single RF microwave antenna 108 typically a quarter-wave dipole antenna, which is located in a bore 110 formed in forward section 102. The cross section of the forward section 102 is preferably pear shaped, as illustrated in Fig. 3B, and the antenna 108 is disposed in the broader portion thereof. Preferred dimensions of the forward section are as indicated in Figs. 3A and 3B.

The forward section 102 is typically formed of Teflon and is provided with an additional bore 112 for supply of coolant fluid. Bore 112 terminates in a side outlet 114 which is typically coupled to a flexible conduit 116 having an inner diameter of 2/16th of an inch (3.17 mm) and an outer diameter of 3/16th of an inch (4.76 mm). The flexible conduit 116 is tightly wound about the forward section 102 as illustrated and is kept in place by the provision of a protective sheath 118, typically formed of thin plastic or rubber, which sheath conforms to the ribbed configuration defined by the coils of flexible conduit 116.

Cooling fluid communication to bore 112 and from the outlet of flexible conduit 116 is provided via conduits 120 which extend through handle portion 106 to suitable flexible conduits 122 which are connected to coolant circulation apparatus (not shown).

The probe structure illustrated in Fig. 3A has a number of significant advantages:

1. The forward portion 102 is configured so as to be insertable into the rectum forwardly of the sphincter muscle, so as to enable the sphincter muscle, which operates non-voluntarily, to engage the narrowed intermediate 104 and thus prevent inadvertent dislodgement of the probe from the rectum or undesired translation of the probe relative to the tumor, resulting in incorrect aiming of the heat radiation directed thereto.

2. The provision of cooling conduits between the patient's skin and the probe provides enhanced cooling efficiency.

3. The ribbed structure of the cooling conduits provides increased surface area for enhanced cooling efficiency.

4. The ribbed structure of the cooling conduits also provides enhanced engagement between the probe assembly and the body cavity.

5. The use of flexible conduits for the external cooling conduits, enables these conduits to be compressed as they are inserted, for ease of insertion and then to be expanded as a coolant is circulated therethrough for enhanced engagement with the body cavity to prevent inadvertent slippage.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the invention is defined only by the claims which follow:

Claims

1. Apparatus suitable for hyperthermic treatment of tumours in the vicinity of the anal body cavity whereby the cavity mucosa and the cavity walls are cooled while simultaneously heating said tumours, said apparatus comprising:

probe means (101) arranged to be insertable into the body cavity and including;

a housing having forward and intermediate surfaces (102, 104); radiation-producing antenna means (108; 130) disposed in said housing; and

cooling conduit means (116) disposed peripherally of said housing and arranged to receive cooling fluid for cooling body tissue disposed in propinquity thereto, said cooling conduit means comprising a flexible conduit, characterized by said flexible conduit (116) being coiled about the outside forward peripheral surface (102) of said housing, whereby it may be compressed upon insertion into the anal cavity and expanded forwardly of the sphincter muscle when coolant passes therethrough for secure engagement in said cavity, thus retained by the sphincter muscle.

2. Apparatus according to claim 1 and wherein said coiled conduit (116) defines a ribbed outer surface.

3. Apparatus according to claim 1 and wherein said housing defines a relatively broad cross section forward portion (102) and a narrower intermediate portion (104), said forward portion having said antenna means (108; 130) defined therein and being surrounded by said cooling conduit means (116).

4. Apparatus according to claim 1 and wherein said probe means also comprises temperature sensing means (12).

5. Apparatus according to claim 4 and wherein said temperature sensing means (12) comprise means for sensing the temperature at tissue adjacent said probe means along the radiation path between said antenna means and a tumour.

6. Apparatus according to claim 4 and wherein said temperature sensing means (12) comprise means for sensing the temperature in the vicinity of or inside said tumour.

7. Apparatus according to claim 4 and wherein said temperature sensing means (12) comprise

means for sensing the temperature within said cooling conduit means.

8. Apparatus according to claim 4 and also comprising means (14, 16, 18) for governing the power radiated by said antenna means in accordance with the temperature sensed by temperature sensing means.

Patentansprüche

- 10 1. Vorrichtung, geeignet zur hyperthermischen Behandlung von Tumoren in der Nachbarschaft der analen Leibeshöhle, wodurch die Höhlenmucosa und die Hölenwände gekühlt werden, während gleichzeitig die Tumore erhitzt werden, wobei die Vorrichtung aufweist:
eine Sondeneinrichtung (111), die in die Leibeshöhle einführbar ist und umfaßt;
ein Gehäuse, das Vorder- und Zwischenflächen (102, 104) hat; eine Strahlung erzeugende Antenneneinrichtung (108, 130), die in dem Gehäuse angeordnet ist; und
eine Kühlleitungseinrichtung (116), die am Umfang des Gehäuses angeordnet und so ausgebildet ist, daß sie Kühlfluid zum Kühlen des Körpergewebes empfängt, das in ihrer Nähe angeordnet ist, wobei die Kühlleitungseinrichtung eine flexible Leitung umfaßt,
dadurch gekennzeichnet, daß die flexible Leitung (116) um die äußere vordere Umfangsfläche (102) des Gehäuses gewickelt ist, wodurch sie bei dem Einführen in die Analhöhle zusammengedrückt und vorderhalb des Schließmuskels aufgeweitet werden kann, wenn Kühlmittel durch sie hindurchgeht, zur sicheren Befestigung in der Höhle, so daß sie durch den Schließmuskel festgehalten wird.
- 20 2. Vorrichtung nach Anspruch 1, wobei die gewickelte Leitung (116) eine gerippte äußere Oberfläche bildet.
- 25 3. Vorrichtung nach Anspruch 1, wobei das Gehäuse einen vorderen Teil (102) relativ breiten Querschnittes und einen schmaleren Zwischenteil (104) hat, wobei der vordere Teil die Antenneneinrichtung (108; 130) enthält und durch die Kühlleitungseinrichtung (116) umgeben ist.
- 30 4. Vorrichtung nach Anspruch 1, wobei die Sondeneinrichtung außerdem eine Temperatursensoreinrichtung (12) aufweist.
- 35 5. Vorrichtung nach Anspruch 4, wobei die Temperatursensoreinrichtung (12) eine Einrichtung aufweist zum Abfühlen der Temperatur an Gewebe neben der Sondeneinrichtung längs des Strahlungsweges zwischen der Antenneneinrichtung und einem Tumor.
- 40 6. Vorrichtung nach Anspruch 4, wobei die Temperatursensoreinrichtung (12) eine Einrichtung aufweist zum Abfühlen der Temperatur in der Nachbarschaft oder innerhalb des Tumors.
- 45 7. Vorrichtung nach Anspruch 4, wobei die Temperatursensoreinrichtung (12) eine Einrichtung aufweist zum Abfühlen der Temperatur innerhalb der Kühlleitungseinrichtung.
- 50 8. Vorrichtung nach Anspruch 4, die außerdem

eine Einrichtung (14, 16, 18) aufweist zum Steuern der durch die Antenneneinrichtung abgestrahlten Leistung gemäß der durch die Temperatursensor-einrichtung abgeführten Temperatur.

Revendications

1. Appareil approprié pour le traitement par hyperthermie de tumeurs se trouvant au voisinage de la cavité anale du corps humain, dans lequel on refroidit la muqueuse de la cavité et les parois de la cavité tout en chauffant simultanément les tumeurs, cet appareil comprenant une sonde (101) agencée de manière à pouvoir être introduite dans la cavité du corps et comportant un boîtier ayant des sections antérieure et intermédiaire (102, 104), une antenne (108, 130), émettant un rayonnement, disposée dans le boîtier et un conduit de refroidissement (116) disposé à la périphérie du boîtier et agencé de manière à recevoir un fluide de refroidissement pour refroidir les tissus du corps se trouvant à proximité, ce conduit de refroidissement comprenant un conduit flexible, caractérisé en ce que le conduit flexible (116) est bobiné autour de la surface périphérique externe de la section antérieure (102) du boîtier si bien qu'il peut être comprimé lors de l'insertion de la sonde dans la cavité anale et qu'il peut ensuite être dilaté en avant du sphincter lorsque le fluide de refroidissement passe à travers lui, afin d'assurer un maintien ferme dans la cavité, en étant ainsi retenu par le sphincter.

2. Appareil suivant la revendication 1 caracté-

risé en ce que le conduit bobiné (116) définit une surface externe nervurée.

3. Appareil suivant la revendication 1 caractérisé en ce que le boîtier définit une portion antérieure (102) de section transversale relativement large et une portion intermédiaire (104) plus étroite, cette portion antérieure contenant l'antenne (108, 130) et étant entourée par le conduit de refroidissement (166).

4. Appareil suivant la revendication 1 caractérisé en ce que la sonde comprend également des moyens (12) de détection de la température.

5. Appareil suivant la revendication 4 caractérisé en ce que les moyens (12) de détection de la température comprennent des moyens détectant la température du tissu adjacent à la sonde le long du trajet du rayonnement entre l'antenne et une tumeur.

6. Appareil suivant la revendication 4 caractérisé en ce que les moyens (12) de détection de la température comprennent des moyens pour détecter la température au voisinage de la tumeur ou à l'intérieur de celle-ci.

7. Appareil suivant la revendication 4 caractérisé en ce que les moyens (12) de détection de la température comprennent des moyens pour détecter la température dans le conduit de refroidissement.

8. Appareil suivant la revendication 4 caractérisé en ce qu'il comprend des moyens (14, 16, 18) pour commander la puissance du rayonnement émis par l'antenne en fonction de la température détectée par les moyens de détection de la température.

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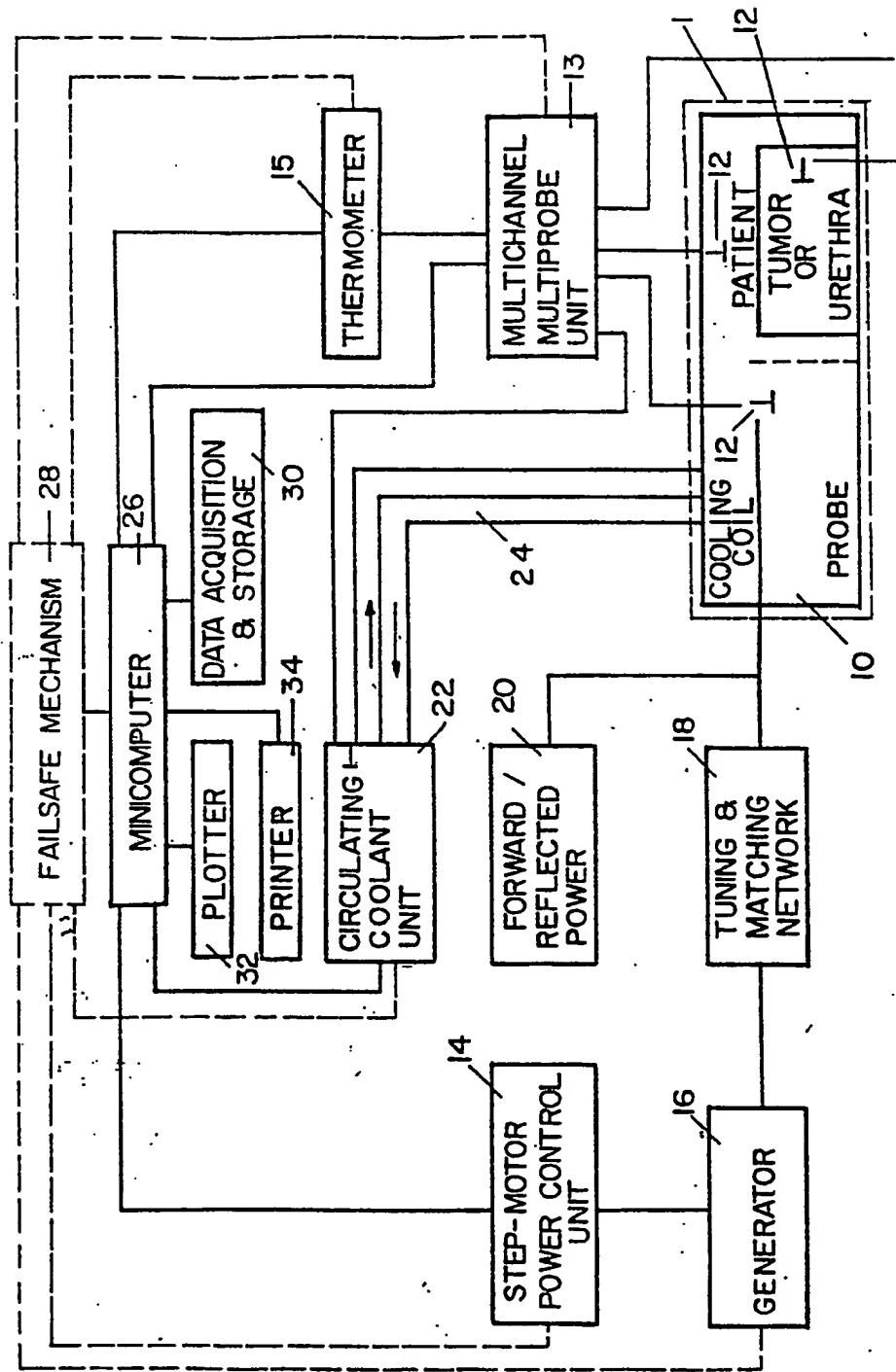
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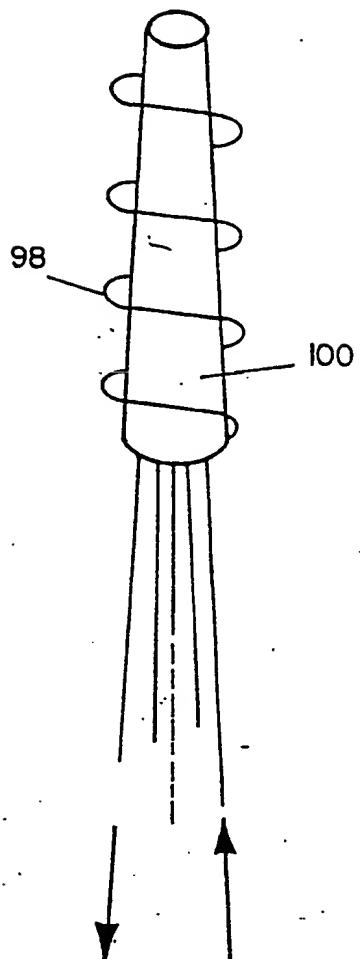


FIG. / 2

